

The opinion in support of the decision being entered today was not written for publication and is not binding precedent of the Board.

Paper No. 31

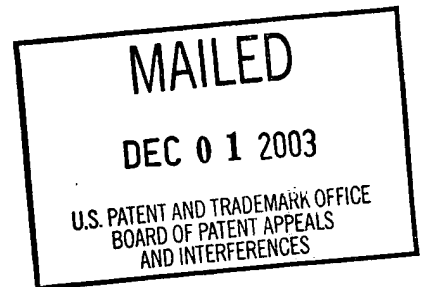
UNITED STATES PATENT AND TRADEMARK OFFICE

**BEFORE THE BOARD OF PATENT APPEALS
AND INTERFERENCES**

Ex parte OLGA BANDMAN,
PREETI LAL, and PURVI SHAH

Appeal No. 2003-1607
Application No. 09/265,710

ON BRIEF



Before WINTERS, WILLIAM F. SMITH, and GRIMES, Administrative Patent Judges.

GRIMES, Administrative Patent Judge.

REMAND TO THE EXAMINER

The following matter must be addressed before we reach the merits of the issue on appeal.

1. The Furness declaration

In response to a nonfinal Office action, Appellants filed a declaration under 37 CFR § 1.132 by Lars Michael Furness. See Paper No. 20, filed Feb. 19, 2002. The examiner responded to the declaration as follows:

The declaration by Lars Furness under 37 CFR 1.132 . . . is insufficient to overcome the rejection of claims 1, 2, 12, 21, 42 to 45 and 48 to 51 based upon a lack of specific and substantial utility as

set forth in the last Office action because it merely presents Applicant's [sic] arguments of record in declaratory form such arguments having already been answered on the record.

Paper No. 21, mailed May 7, 2002. This treatment of the Furness declaration is repeated verbatim in the Examiner's Answer. See pages 12-13.

Thus, it is apparent that the Furness declaration is part of the administrative record for review on appeal. The examiner, however, has not adequately responded to the declaratory evidence.

Declaratory evidence, such as the Furness declaration, is not merely the presentation of argument in a different form. A Rule 132 declaration is evidence. If an examiner does not respond substantively to a declaration, the opinions or conclusions presented therein become unrebutted evidence, regardless of how well or how poorly those opinions or conclusions are supported. Since the Furness declaration is part of the evidence of record, the examiner must take the further step of explaining why Appellants' arguments, as supported by the declaratory evidence, are not persuasive.

"All entered affidavits, declarations, and other evidence traversing rejections are acknowledged and commented upon by the examiner in the next succeeding action. . . . Where the evidence is insufficient to overcome the rejection, the examiner must specifically explain why the evidence is insufficient. General statements such as 'the declaration lacks technical validity' or 'the evidence is not commensurate with the scope of the claims' without an explanation supporting such findings are insufficient." Manual of Patent

Examining Procedure § 716.01. See also In re Rinehart, 531 F.2d 1048, 1052, 189 USPQ 143, 147 (CCPA 1976):

When prima facie obviousness is established and evidence is submitted in rebuttal, the decision-maker must start over. . . . Facts established by rebuttal evidence must be evaluated along with the facts on which the earlier conclusion was reached, not against the conclusion itself. Though the tribunal must begin anew, a final finding of obviousness may of course be reached, but such finding will rest upon evaluation of all facts in evidence, uninfluenced by any earlier conclusion reached . . . upon a different record.

The approach set out in Rinehart also applies to rejections under other sections of the statute: when evidence is submitted in rebuttal, the examiner must take a step back and consider the rejection anew, based on all the facts in the record.

On return of this application, the examiner should respond substantively to the evidence set forth in the Furness declaration filed Feb. 19, 2002 (Paper No. 20). In particular, the examiner should consider and address the following questions: (1) Does the evidence relied on in the declaration support the conclusions drawn by Mr. Furness?, and (2) Do Mr. Furness' conclusions adequately establish or support the utility of the claimed invention, so as to overcome the rejections for lack of utility?

In considering these questions, the examiner should keep in mind how the utility requirement has been interpreted by the courts. The seminal decision interpreting § 101's utility requirement is Brenner v. Manson, 383 U.S. 519, 148 USPQ 689 (1966). The invention claimed in Brenner was a chemical process, which had been rejected for lack of utility because the product of the process had not been shown to be useful. See id. at 521-22, 148 USPQ at 690.

The Brenner Court noted that the meaning of “useful” was somewhat unclear when applied to a chemical process:

Even if we knew precisely what Congress meant in 1790 when it devised the “new and useful” phraseology and in subsequent re-enactments of the test, we should have difficulty in applying it in the context of contemporary chemistry, where research is as comprehensive as man’s grasp and where little or nothing is wholly beyond the pale of “utility”—if that word is given its broadest reach.

Id. at 530, 148 USPQ at 694.¹

The Court concluded that “[t]he basic quid pro quo contemplated by the Constitution and the Congress for granting a patent monopoly is the benefit derived by the public from an invention with substantial utility. Unless and until a process is refined and developed to this point—where specific benefit exists in currently available form—there is insufficient justification for permitting an applicant to engross what may prove to be a broad field.” Id. at 534-35, 148 USPQ at 695.

Subsequent decisions of the CCPA and the Federal Circuit have further developed the requirements of “utility”. The first opinion of the CCPA applying Brenner was In re Kirk, 376 F.2d 936, 153 USPQ 48 (CCPA 1967). Kirk involved a set of steroid derivatives said to be of value “in the furtherance of steroidal research and in the application of steroidal materials to veterinary or medical practice.” Id. at 938, 153 USPQ at 50. The claims had been rejected for lack of utility.

¹ The invention at issue in Brenner was a process, but the Court expressly noted that its holding “would apply equally to the patenting of the product produced by the process.” Id. at 535, 148 USPQ at 695-96.

Similarly to the present application, the applicants in Kirk submitted an affidavit to overcome the rejection. The affidavit purportedly “show[ed] that one skilled in the art would be able to determine the biological uses of the claimed compounds by routine tests.” Id. at 939, 153 USPQ at 51. The court held that the affidavit did not overcome the rejection: “the sum and substance of the affidavit appear[ed] to be that one of ordinary skill in the art would know ‘how to use’ the compounds to find out in the first instance whether the compounds are—or are not—in fact useful or possess useful properties, and to ascertain what those properties are.” Id. at 942, 153 USPQ at 53.

The Kirk court also interpreted Brenner as holding that usefulness to chemists doing research is not enough to satisfy § 101. “There can be no doubt that the insubstantial, superficial nature of vague, general disclosures or arguments of ‘useful in research’ or ‘useful as building blocks of value to the researcher’ was recognized, and clearly rejected, by the Supreme Court” in Brenner. See Kirk, 376 F.2d at 945, 153 USPQ at 55.

On the other hand, the courts reversed utility rejections in In re Jolles, 628 F.2d 1322, 206 USPQ 885 (CCPA 1980); Cross v. Iizuka, 753 F.2d 1040, 224 USPQ 739 (Fed. Cir. 1985); and In re Brana, 51 F.3d 1560, 34 USPQ2d 1436 (Fed. Cir. 1995). In each of these cases, the applicants had shown, by either in vivo or in vitro testing, that the claimed products had a specific biological activity that made them useful to persons skilled in the art. See Jolles, 628 F.2d at 1323-24, 206 USPQ at 887-88 (declaratory evidence showed the claimed compositions were effective in treating leukemia in a mouse model and in humans); Cross, 753

F.2d at 1051, 224 USPQ at 748 (evidence showed successful in vitro testing of claimed compounds, plus similar in vitro and in vivo activities of structurally similar compounds); Brana, 51 F.3d at 1562, 34 USPQ2d at 1438 (claimed compounds shown to have in vivo antitumor activity in mice, and disclosed to have higher antitumor activity than related compound with known antitumor activity).

Several lessons can be drawn from the cases discussed above. First, § 101's requirement that an invention be "useful" is not to be given its broadest reach, such that little or nothing of a chemical nature would be found to lack utility. See Brenner, 383 U.S. at 530, 148 USPQ at 694. Thus, not every "use" that can be asserted will be sufficient to satisfy § 101. For example, "vague, general disclosures or arguments of 'useful in research' or 'useful as building blocks of value to the researcher'" do not satisfy § 101. See Kirk, 376 F.2d at 945, 153 USPQ at 55 (interpreting Brenner).

Rather, § 101 requires a utility that is "substantial", i.e., one that provides a specific benefit in currently available form. Brenner, 383 U.S. at 534-35, 148 USPQ at 695. This standard has been found to be met where applicants have provided in vitro or in vivo data showing that a claimed compound has a specific biological activity that makes it useful to those skilled in the relevant art. See Jolles, 628 F.2d at 1327-28, 206 USPQ at 891; Cross, 753 F.2d at 1051, 224 USPQ at 748; and Brana, 51 F.3d at 1567, 34 USPQ2d at 1442.

It may also interest the examiner to note that the Board has recently decided appeals in three applications assigned to the same assignee as the instant application. Rejections for lack of utility were affirmed in applications

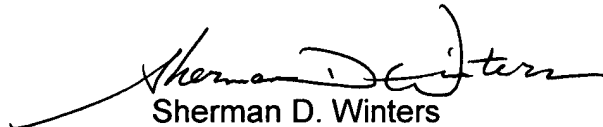
09/002,485 and 09/209,859, while a rejection on the same basis was reversed in application 09/212,147. Copies of the decisions should be of record in the above applications, if the examiner wishes to consult them.

2. Future proceedings in this application

We authorize the examiner to enter a Supplemental Examiner's Answer limited to responding to the Furness declaration. In response to the Supplemental Examiner's Answer, Appellants are entitled to file a Supplemental Reply Brief.

This application, by virtue of its "special" status, requires an immediate action. The Manual of Patent Examining Procedure (MPEP) § 708.01 (8th ed., August 2001). It is important that the Board be informed promptly of any action affecting the appeal in this case.

REMANDED


Sherman D. Winters
Administrative Patent Judge


William F. Smith
Administrative Patent Judge


Eric Grimes
Administrative Patent Judge

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